

CLINICAL RESEARCH

Interventional Cardiology

Transcatheter Aortic Valve Replacement With the St. Jude Medical Portico Valve

First-in-Human Experience

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Objectives	The purpose of this study was to demonstrate the feasibility and procedural outcomes with a new self-expanding and repositionable transcatheter heart valve.
Background	Transcatheter aortic valve replacement is a viable option for selected patients with severe symptomatic aortic stenosis. However, suboptimal prosthesis positioning may contribute to paravalvular regurgitation, atrioventricular conduction block, and mitral or coronary compromise.
Methods	The repositionable Portico valve (St. Jude Medical, Minneapolis, Minnesota) was implanted in 10 patients with severe aortic stenosis utilizing percutaneous femoral arterial access. Patients underwent transthoracic and transesophageal echocardiography and multidetector computed tomography before and after valve implantation. Clinical and echocardiographic follow-up was obtained at 30 days.
Results	Device implantation was successful in all patients. Prosthesis recapture and repositioning was performed in 4 patients. Intermittent prosthetic leaflet dysfunction in 1 patient required implantation of a second transcatheter valve. There was 1 minor stroke. At 30-day follow-up, echocardiographic mean transaortic gradient was reduced from 44.9 ± 16.7 mm Hg to 10.9 ± 3.8 mm Hg ($p < 0.001$), and valve area increased from 0.6 ± 0.1 cm ² to 1.3 ± 0.2 cm ² ($p < 0.001$). Paravalvular regurgitation was mild or less in 9 patients (90%) and moderate in 1 patient (10%). There were no major strokes, major vascular complications, major bleeds, or deaths. No patient required pacemaker implantation. All patients were in New York Heart Association functional class II or less.
Conclusions	Transcatheter aortic valve replacement with the repositionable Portico transcatheter heart valve is feasible, with good short-term clinical and hemodynamic outcomes. (J Am Coll Cardiol 2012;60:581–6) © 2012 by the American College of Cardiology Foundation

New transcatheter heart valves (THV) may attempt to improve on the limitations of current systems. Potentially desirable enhancements may reduce vascular injury, improve the ease and accuracy of positioning and deployment, or improve paravalvular sealing. The ability to reposition,

recapture, redeploy, or remove a partially or fully deployed THV may be particularly desirable when the initial implant positioning is suboptimal. We describe the first-in-human experience with the self-expanding repositionable Portico THV (St. Jude Medical, Minneapolis, Minnesota).

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Abbreviations and Acronyms

LVEF = left ventricular ejection fraction
MDCT = multidetector computed tomography
TAVR = transcatheter aortic valve replacement
TEE = transesophageal echocardiography
THV = transcatheter heart valve
TTE = transthoracic echocardiography

Methods

Patients. Transcatheter aortic valve replacement (TAVR) was performed in 10 high-risk patients with severe symptomatic aortic stenosis at 2 centers (St. Paul's Hospital, Vancouver, British Columbia, and the Quebec Heart and Lung Institute, Quebec City, Quebec) between June and September 2011. All patients gave informed, written consent. Inclusion criteria are documented in Table 1.

Valve and delivery system. The trileaflet Portico THV consists

of a nitinol self-expanding frame, bovine pericardial leaflets, and a porcine pericardial sealing cuff (Fig. 1). The outflow portion of the stent frame incorporates 3 retention tabs, which secure the crimped valve to the delivery system. The Portico valve is sized according to the nominal external stent diameter at the valvular level. Currently, only the 23-mm device is available.

The catheter consists of a soft tapered nose cone, an 18F capsule that contains the compressed valve, and a 12F shaft. A handle incorporates mechanisms to unsheath and release the valve using a rotating thumbwheel.

Procedures. All procedures were performed under general anesthesia with transesophageal echocardiography (TEE). The common femoral artery was punctured (1), and an 18F Ultimium sheath (St. Jude Medical) or Drysheath (Gore Medical, Newark, Delaware). Rapid ventricular pacing was not utilized during THV deployment. The delivery catheter was advanced over a guidewire (Amplatz Extra-Stiff 0.0035 inch, Cook Medical, Bloomington, Indiana) into the left ventricle (Fig. 2). By rotating the thumbwheel, the inflow of the THV was unsheathed until slightly flared. The THV was then withdrawn to approximately 5 mm to 8 mm below the basal insertion of the native leaflets, as determined by angiography. By further rotating the thumbwheel, the annular portion of the THV was fully deployed. At this time, the valve leaflets will be fully functional, and the retention tabs remain secure within the capsule (Online Videos 1 and 2).

The position of the functioning THV was then assessed by TEE and aortography. If not satisfactory, then THV repositioning could be accomplished by traction on the delivery catheter. Alternatively, and preferably, rotating the thumbwheel in a reverse direction allows the THV to be partially or completely recaptured, enabling the THV to be redeployed or removed. When a satisfactory position was achieved, the thumbwheel was fully rotated to release the THV.

The access site was closed percutaneously (ProGlide, Abbott, Abbott Park, Illinois). The transvenous pacing wire was generally removed at the completion of the procedure. Patients were monitored for at least 48 h before discharge.

Table 1 Selection Criteria for St. Jude Medical 23-mm Portico Transcatheter Heart*

Characteristic	Noninvasive			Angiography			Selection Criteria	
	Echo	CT/MRI	LV	Aortic	Coronary	Vascular	Acceptable	Not Acceptable
Atrial or ventricular thrombus	X						Not present	Present
Mitral regurgitation	X						Grade ≤2	Grade >2
LV ejection fraction	X		X				>20%	<20%
LV hypertrophy	X						Normal to mild (0.6–1.8 cm)	Severe (>2 cm)
Subaortic stenosis	X	X					Not present	Present
Annulus diameter	X	X					19–21 mm	<19 mm or >21 mm
Annulus to aorta (angle)†		X	X	X			<30°	>45°
Sinus of Valsalva width	X	X	X	X			≥27 mm	<27 mm
Sinus of Valsalva height	X	X	X	X	X		≥15 mm	<15 mm
Coronary ostia position vs. calcium distribution	X	X			X		High, minimal risk Ca ²⁺ interference	Low, high risk Ca ²⁺ interference
Coronary artery disease					X		None	Untreated proximal stenosis ≥70%
Ascending aorta diameter	X		X	X			28–36 mm	<26 mm or >38 mm
Aortic arch angulation	X			X		X	Large radius turn	High angulation or sharp bend
Aortic and vascular disease‡	X					X	None	Ascending or transverse arch mobile atheromata
Vascular access diameter	X					X	>6 mm	<6 mm
Annulus eccentricity	X						Minor/major axis ratio ≥0.7	Minor/major axis ratio <0.7

*Manufacturer's recommendations. †Within the first 7 cm of the ascending aorta versus a perpendicular line across the aortic valve. ‡Evaluation for evidence and degree of calcification, observation, tortuosity, and ulceration. CT = computed tomography; Echo = echocardiography; LV = left ventricular; MRI = magnetic resonance imaging; NA = not applicable.

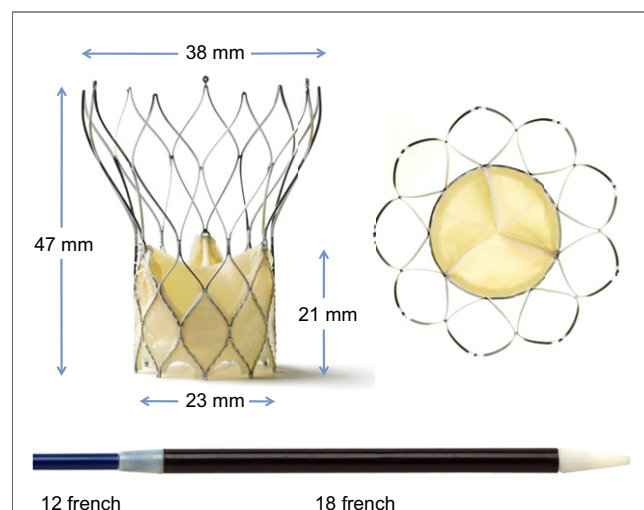


Figure 1 Portico Transcatheter Heart Valve

The 23-mm trileaflet Portico transcatheter heart valve consists of a nitinol self-expandable stent and bovine pericardial leaflets, with an 18-F delivery catheter.

Imaging. Screening included transthoracic echocardiography (TTE), and coronary, aortic root, and descending angiography, as well as cardiac, aortic, and iliofemoral multidetector computed tomography (MDCT) angiography. The TEE and aortic root angiography were performed before and after implantation. The TTE was repeated before hospital discharge and at 1 month (2).

Depth of implant from the base of the coronary cusps to the inflow of the THV was measured on post-implant angiography (3). The THV dimensions at the inflow, valvular, and outflow level were measured by post-implant MDCT (Fig. 4) (4–6). A circular THV was defined by an eccentricity score $<10\%$ (eccentricity = 1 minus minimum external stent diameter divided by maximum external stent diameter) (4,6). The THV expansion was calculated as external THV area divided by nominal external THV area, where 100% represents a fully expanded valve (4). Nominal external THV area is 4.15 cm^2 at the inflow and valvular level and 11.3 cm^2 at the outflow.

Statistical analysis. Continuous variables are described as mean \pm SD or medians with interquartile range. Categorical variables are described by frequencies and percentages. Continuous parametric variables were compared using the paired Student *t* test. All *p* values <0.05 were considered significant. Valve Academic Research Consortium reporting guidelines were utilized (7).

Results

Baseline characteristics. Clinical characteristics are listed in Table 2. Pre-procedural MDCT was performed in 7 patients (3 had renal dysfunction). The MDCT-derived mean annular diameter was $20.6 \pm 1.7 \text{ mm}$, and MDCT annular area was $3.5 \pm 0.5 \text{ cm}^2$.

Outcomes. Prosthetic valve delivery, deployment, removal of the delivery system, and percutaneous vascular closure were successful in all cases. Initial positioning of the

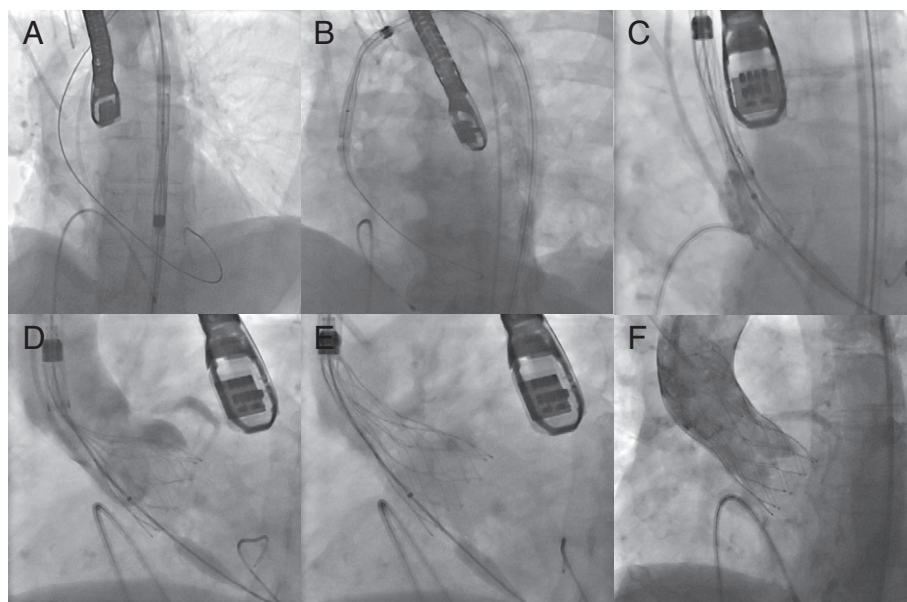


Figure 2 Delivery and Deployment of Portico THV

(A) The fully sheathed transcatheter heart valve (THV). (B) Transversing the aortic arch. (C) The THV is flared in the left ventricular outflow tract. (D) The THV is functional during positioning. (E) Recapture is possible if required. (F) Post-deployment angiography demonstrates a competent valve and patent left coronary artery.

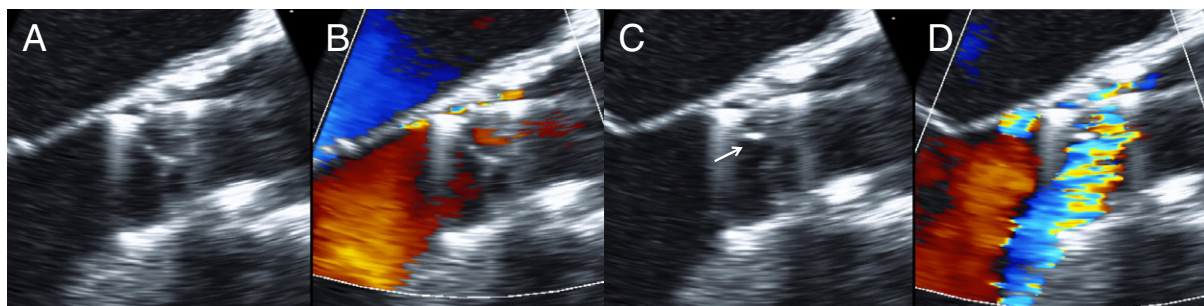


Figure 3 Intermittent Transvalvular Regurgitation

(A) Normal leaflet closure. (B) Mild paravalvular leak. (C) Incomplete closure of a single leaflet (arrow) adjacent to the site of paravalvular regurgitation. (D) Transvalvular regurgitation. A second transcatheter heart valve was implanted with resolution of the paravalvular leak and normal valve function.

expanded valve was suboptimal in 4 patients. In all cases, recapture and repositioning of the valve was easily accomplished without withdrawing the system out of the aortic root.

At 30-day follow-up, there were no deaths, myocardial infarctions, major or minor bleeds, or major vascular complications (Table 3). One patient had a minor stroke

(modified Rankin score 1) (8). There was 1 minor vascular complication (hematoma).

New left bundle branch block developed in 2 patients. None of 9 patients without a pre-existing pacemaker required insertion of a permanent pacemaker. The mean depth of implant was 6.4 ± 1.0 mm below the non-coronary cusp and 7.0 ± 1.5 mm below the left coronary cusp.

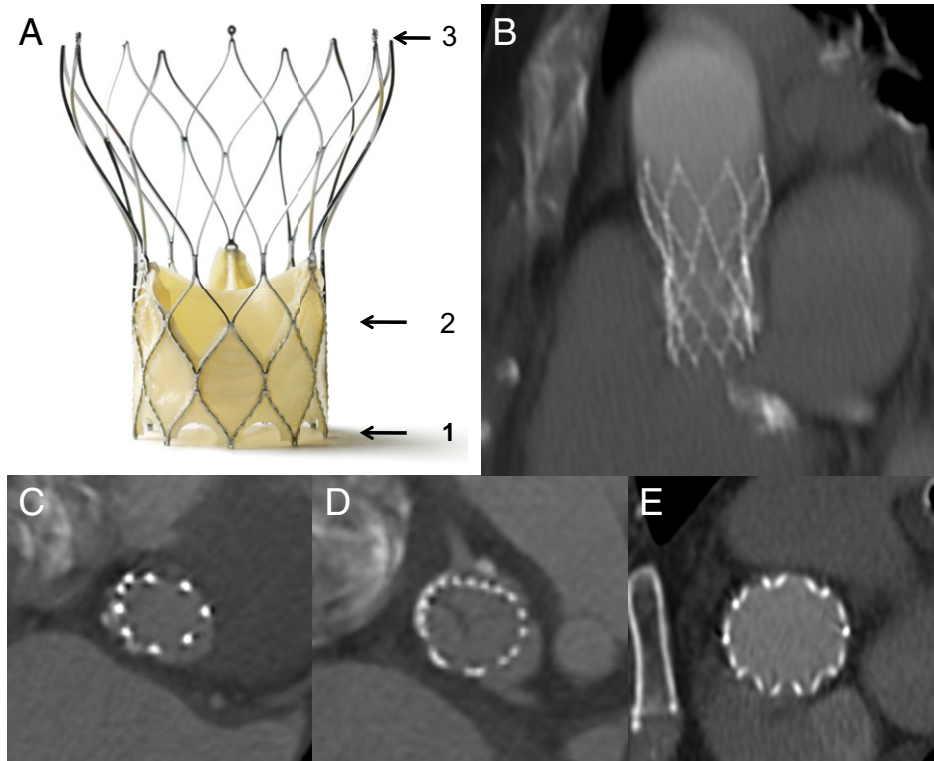


Figure 4 Portico Stent Eccentricity

(A) Stent eccentricity was assessed by multidetector computed tomography (MDCT) at the inflow, valvular, and outflow stent levels. (B) MDCT 3-dimensional reconstruction of the Portico valve. As demonstrated in 1 case, the stent eccentricity varied from the (C) inflow level, 13.6%, (D) valvular level, 5.7%, and (E) outflow level, 0%.

Table 2	Baseline Characteristics (N = 10)
Age, yrs	82.4 ± 5.7
Female	10 (100%)
Diabetes mellitus	5 (50%)
Height, m	1.58 ± 0.09
Weight, kg	58.0 (50.5, 67.1)
Prior CABG	1 (10%)
Prior pacemaker	1 (10%)
COPD	2 (20%)
Frailty	7 (70%)
Porcelain aorta	1 (10%)
STS PROM, %	8.1 ± 3.2
NYHA functional class pre-TAVR	
I	0 (0%)
II	2 (20%)
III	8 (80%)
IV	0 (0%)
Glomerular filtration rate, ml/min	47.1 ± 18.8
Mean TEE aortic annulus diameter, mm	19.4 ± 1.6
Mean AVA, cm ²	0.62 ± 0.15
Mean transaortic gradient, mm Hg	44.5 ± 17.5
LVEF, %	57.3 ± 13.8
Moderate or severe mitral regurgitation	5 (50%)

Values are mean ± SD, median (25th to 75th percentile), or n (%).

AVA = aortic valve area, CABG = coronary artery bypass surgery, COPD = chronic obstructive pulmonary disease; LVEF = left ventricular ejection fraction; TEE = transesophageal echocardiography; STS PROM = Society of Thoracic Surgeons predicted risk of mortality; TAVR = transcatheter aortic valve replacement.

Transaortic gradient decreased from 44.9 ± 16.7 mm Hg to 10.7 ± 4.5 mm Hg ($p < 0.001$), and aortic valve area increased from 0.6 ± 0.1 cm² to 1.4 ± 0.2 cm² ($p < 0.001$) (Table 4). Paravalvular regurgitation as assessed by TTE at hospital discharge was trivial or less in 4 (40%), mild in 5 (50%), and moderate in 1 (10%).

One patient with a calcified eccentric annulus (18.4 × 24.4 mm by MDCT) and a small hypermobile calcific valvular nodule had severe transvalvular regurgitation after Portico implantation and release. There was a moderate paravalvular leak, and the THV appeared to be positioned slightly low. Consequently, 1 of the 3 retention tabs was snared (Gooseneck, AGA Medical, Minneapolis, Minnesota), and the THV was pulled a few millimeters higher. Paravalvular regurgitation was reduced to mild, and transvalvular regurgitation disappeared. Post-procedure severe transvalvular regurgitation recurred intermittently. The TEE suggested that was due to intermittent failure of a single, otherwise normal leaflet adjacent to the paravalvular leak (Fig. 3). A second 23-mm Portico THV was implanted within the first valve (THV-in-THV) 7 days later. There was complete resolution of the valvular insufficiency with residual trivial paravalvular insufficiency, a mean gradient of 14 mm Hg, and valve area of 1.4 cm².

Follow-up. At 30 days all patients remained alive. New York Heart Association functional class was I in 6 patients (75%) and class II in 4 patients (25%). The 30-day echocardiography documented a mean transaortic gradient of 10.9 ± 3.8 mm Hg ($p < 0.001$) and mean

aortic valve area of 1.3 ± 0.2 cm² ($p < 0.001$). All patients were discharged from hospital, and no patient required rehospitalization. Paravalvular regurgitation was none or trace in 5 patients (50%), mild in 4 (40%), and moderate in 1 patient (10%). No patient had more than trivial transvalvular regurgitation.

THV expansion. All patients underwent post-implantation MDCT before hospital discharge (Fig. 4). Aortic annular eccentricity pre-TAVR was greater than inflow THV eccentricity (20.1 ± 6.2% vs. 12.8 ± 6.1%, $p < 0.01$). The THV eccentricity was maximal at the inflow (12.8 ± 6.1%) and valvular level (12.0 ± 7.3%), and least at the outflow (2.4 ± 1.2%). The THV with intermittent leaflet dysfunction was 18% eccentric at the valvular level. Circularity was seen in 4 valves at the inflow and valvular level and 10 at the outflow level. Mean THV expansion was 88.2 ± 16.6% at the inflow, 88.1 ± 10.5% at the valvular level, and 65.0 ± 9.1% at the outflow.

Discussion

We document the first-in-human experience with the Portico self-expanding transcatheter aortic bioprosthesis. The Portico THV was delivered and deployed successfully in all patients. There were no major periprocedural complications. All patients in this high-risk cohort remained alive at 30 days with a marked improvement in functional class.

Recapture and positioning. A desirable feature is the potential to be deployed to the point of functionality while allowing for controlled recapture, followed either by repositioning and redeployment or by removal. Recapture and repositioning was successfully accomplished in 4 patients. The ability to reposition the valve may be helpful in reducing the likelihood of problematic paravalvular regurgitation, coronary obstruction, mitral interference, and atrioventricular block.

Atrioventricular block. Although numbers were small, the absence of high-grade block requiring pacemaker implantation is reassuring. In comparison, the rates of pacemaker implantation due to new conduction block have been high with the self-expandable CoreValve device (Medtronic, Minneapolis, Minnesota), likely as a consequence of septal

Table 3	30-Day Outcome for the 23-mm Portico Valve
Death	0 (0%)
Myocardial infarction	0 (0%)
Major stroke	0 (0%)
Minor stroke	1 (10%)
Major vascular complication	0 (0%)
Minor vascular complication	1 (10%)
Acute kidney injury, modified RIFLE criteria stage 3	0 (0%)
Repeat procedure for valve-related dysfunction	1 (10%)
Permanent pacemaker implantation	0 (0%)
Readmission to hospital	0 (0%)

Values are n (%).

RIFLE = risk, injury, failure, loss, end-stage kidney disease.

Table 4 Hemodynamic Function After Implantation and at 30-Day Follow-Up

Case #	Pre-TAVR			Post-TAVR, Pre-Hospital Discharge				1-Month Post-TAVR			
	AVA, cm ²	MG, mm Hg	LVEF, %	AVA, cm ²	MG, mm Hg	PAR	TAR	AVA, cm ²	MG, mm Hg	PAR	TAR
1	0.5	59	65	1.0	14	Mild	None	1.0	15	Mild	None
2	0.5	28	30	1.8	4	Moderate	Trivial	1.6	4	Moderate	Trivial
3	0.7	35	70	1.5	6	Trivial	None	1.5	10	Trivial	None
4	0.6	38	35	1.4	13	Mild	Severe	1.4	14	Trivial	None
5	0.8	39	60	1.5	8	Trivial	None	1.3	8	Trivial	None
6	0.4	56	58	1.3	10	Trivial	None	1.2	10	Trivial	None
7	0.6	40	60	1.1	16	Mild	None	1.1	11	Mild	None
8	0.6	45	60	1.3	10	Trivial	None	1.2	15	Trivial	None
9	0.5	82	70	1.4	18	Mild	None	1.6	7	Mild	None
10	0.8	27	69	1.4	8	Mild	None	1.3	10	Mild	None
Mean ± SD	0.6 ± 0.1	44.9 ± 16.7	54.7 ± 14.3	1.4 ± 0.2	10.7 ± 4.5			1.3 ± 0.2	10.9 ± 3.8		

MG = mean transaortic gradient; PAR = paravalvular regurgitation; TAR = transvalvular aortic regurgitation; TAVR = transcatheter aortic valve replacement; other abbreviations as in Table 2.

compression. Contrasting the 2 devices, the Portico valve does not have a flared inflow (Fig. 1), and the ability to reposition may facilitate higher implantation. Notably, the implant depth was less than has been generally reported with the CoreValve device (3).

Valve function. The mean transaortic gradient of 10.9 mm Hg is comparable to that of other aortic THVs. The mean estimated orifice area of 1.3 cm² is smaller than generally reported; however, the 23-mm nominal valve size was intended for patients with small annulus diameter of 18 mm to 21 mm. By way of comparison, the 23-mm SAPIEN/SAPIEN XT valve (Edwards Lifesciences, Irvine, California) implanted into patients with small annuli <20 mm by TEE had a mean orifice area of 1.4 cm² (8).

Prosthetic valve dysfunction was observed in a single case. The mechanism remains conjectural. In vitro modeling has demonstrated that a highly eccentric stent frame in combination with a paravalvular leak can result in an intermittent “frozen leaflet,” possibly due to equalization of pressures on either side of the leaflet when fully open. Although speculative, it is possible that more aggressive balloon before or after dilation might have resolved this problem. It is reassuring that implantation of a second THV was easily accomplished and that hemodynamic function after THV-in-THV implantation was excellent.

Expansion and eccentricity. Adequate oversizing enables sufficient radial force to secure the THV, ensure effective sealing, and minimize paravalvular regurgitation. Some degree of underexpansion at the inflow level is expected with self-expandable prostheses. The completeness of THV expansion and residual eccentricity of the Portico appeared similar to that of the self-expandable CoreValve device (6).

Conclusions

The Portico transcatheter heart valve is a new bioprosthesis with novel repositioning capabilities. Although this is a

small series and follow-up remains limited, the clinical and echocardiographic outcomes are encouraging. Further evaluation is warranted.

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Key Words: aortic stenosis ■ transcatheter aortic valve implantation ■ transcatheter aortic valve replacement.

APPENDIX

For the supplemental videos, please see the online version of this article.